REMARKS

Claims 8 and 10-12 are pending in this application. Claim 12 has been withdrawn from consideration as non-elected.

I. Claim Rejection Under 35 U.S.C. § 103

The Examiner has rejected claims 8, 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Nagasaka et al. (1995, J. Med. Virol, 46:28-34) in view of Fujimaki et al. (JP 63-239228), Ninomiya et al. (US 5,932,235) and San-Ei Chem (JP 54-070420). Applicants respectfully traverse the rejection.

Claim 8 recites "A Chinese herbal medical composition in the form of jelly, consisting of a Chinese herbal medicine in a base, wherein the Chinese herbal medicine is selected from the group consisting of Kakkon-to and Sho-saiko-to, and is present in an amount less than 60 w/w% per total amount of the composition, wherein the base consists of **0.01 to 10.0 w/w% carrageenan, 0.01 to 10.0 w/w% carob bean gum, and 0.01 to 10.0 w/w% xanthan gum**, per total amount of the composition, and wherein the base does not include a phosphate buffer or agar".

As discussed in detail in the previous responses, the Chinese herbal medical composition of Applicants' claims **unexpectedly improves syneresis, and is unexpectedly superior in long term preservative stability.**

Initially, Applicants respectfully disagree with the basis of the Examiner's rejection. Specifically, none of the cited references teach or suggest the specific combination set forth in Applicants' claims, i.e., Kakkon-to or Sho-saiko-to in a base consisting of the particularly recited amounts of carrageenan, carob bean gum and xanthan gum.

As will be discussed in detail below, each of the references relied upon by the Examiner lacks at least one required aspect of Applicants' composition, or includes a component which is excluded by Applicants' claims.

The Examiner appears to take the position that merely because each of Applicants' recited components is known in the art, it would have been obvious to combine them in the amounts specifically recited by Applicants. However, Applicants kindly assert that this rejection can **only** be based upon impermissible hindsight, as **none** of the references, nor any combination thereof, provides motivation to create Applicants' specific composition with any reasonable

expectation of success.

As the Examiner is certainly aware, a rejection based upon hindsight is improper, and should be avoided. Specifically, as stated by the Supreme Court in KSR International Co. v. Teleflex Inc., "the factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (See KSR International Co. v. Teleflex Inc., 237 S. Ct. 1727 (U.S. 2007), referring to Graham v. John Deere Co. of Kansas City, 86 S. Ct. 684, which warned against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight".

Furthermore, Applicants clearly delineate how each of the references relied upon by the Examiner is deficient, by failing to (1) teach or suggest each of the required limitations, or (2) provide any reason to combine the particular limitations.

Further still, the Examiner states that **absent evidence to the contrary**, the composition is obvious. Applicants respectfully remind the Examiner that evidence of unexpected results has previously been provided and established. Specifically, the Declaration submitted with the response filed April 16, 2007 demonstrates the following:

(1) In Comparative experiment A, a composition (Sho-saiko-to) containing **only carageenan** is **unexpectedly inferior** to a composition (Sho-saiko-to) containing **carageenan, carob bean gum and xanthan gum** in terms of syneresis.

(2) In Comparative experiment B, a composition (Kakkon-to) containing **carageenan** and **carob bean gum** is **unexpectedly far inferior** to a composition (Kakkon-to) containing **carageenan, carob bean gum** and **xanthan gum** in terms of syneresis.

(3) In Comparative experiment C, the composition (Kakkon-to) containing **carageenan** and **carob bean gum** or containing **carageenan** is **unexpectedly inferior** to a composition (Kakkon-to) containing **carageenan, locust bean gum** and **xanthan gum** in terms of syneresis.

Thus, Applicants **have** provided a showing of unexpected results, which demonstrates that the claimed composition would not have been obvious over the art.

Regarding the particular references, Applicants submit the following remarks.

Nagasaka et al.

The Examiner relies upon an abstract of the Nagasaka et al. reference. Applicants submit herewith a full copy of the reference. Applicants note that the Nagasaka et al. reference is almost the same as Kurokawa et al. (JP 07118161), which was previously cited by the Examiner and then withdrawn as a prior art reference. The inventors and authors of the references are nearly the same.

The Nagasaka et al. reference relates to an antiviral agent having low side action by using Kakkon-to as an active component. **However, the agent does not contain carrageenan, carob bean gum or xanthan gum**.

Thus, the reference fails to disclose or suggest a Chinese herbal medical composition in the form of jelly, consisting of a Chinese herbal medicine in a base , "wherein the base consists of **0.01 to 10.0 w/w% carrageenan, 0.01 to 10.0 w/w% carob bean gum, and 0.01 to 10.0 w/w% xanthan gum**, per total amount of the composition", as recited in claim 8, and as acknowledged by the Examiner (see Office Action, page 3, lines 23-25).

Further, the Examiner admits that the reference fails to disclose or suggest Sho-saiko-to.

The reference provides no motivation to combine Kakkon-to or Sho-saiko-to in a base consisting of the particularly recited amounts of carrageenan, carob bean gum and xanthan gum, as required by Applicants' claims.

Accordingly, the presently claimed invention is completely different from the Nagasaka et al. reference.

Fujimaki et al.

As discussed in the previous response, the Fujimaki et al. reference relates to an immunoactivating agent for a person infected by a virus of acquired immune deficiency syndrome, which contains the Chinese medicine, Sho-saik-to. However, the agent does not contain carrageenan, carob bean gum or xanthan gum. Thus, the reference fails to disclose or suggest a base that "consists of **0.01 to 10.0 w/w% carrageenan, 0.01 to 10.0 w/w% carob bean gum, and 0.01 to 10.0 w/w% xanthan gum**, per total amount of the composition", as recited in claim 8.

Thus, similar to the discussion regarding Nagasaka et al., this reference merely demonstrates that Applicants' recited Chinese herbal medicines are known in the art. This reference fails to provide any motivation for combining this particular active in a base consisting

of carrageenan, carob bean gum and xanthan gum, in the particular amounts required by Applicants' claims.

Accordingly, the presently claimed invention is completely different from the Fujimaki et al. reference, and one of ordinary skill in the art would have had no reason or rationale to combine the reference with Nagasaka et al. to arrive at the presently claimed invention.

Ninomiya et al.

As discussed in the last response, the Ninomiya et al. reference relates to a jellied medical composition for oral administration, specifically to a jellied medical composition for oral administration that can easily be taken by patients of advanced age or patients with dysphagia. The Chinese medicines (Kakkon-to and Sho-saiko-to) are not disclosed in this reference.

A base of jelly in the reference contains carrageenan and locust (carob) bean gum, and **preferably further contains polyacrylic acid or a partly neutralized product or a salt thereof**. The reference discloses a base used in a jellied medical composition for oral administration of one or more components selected from gelatin, pectin, xanthan gum, carrageenan, locust bean gum, mannan, etc., more preferably a base containing carrageenan and locust bean gum. In the examples, only a combination of κ-carrageenan and locust bean gum is used.

On the other hand, claim 8 is directed to a Chinese herbal medical composition in the form of jelly consisting of a Chinese herbal medicine in a base, wherein the base specifically **consists of** a combination of carrageenan, carob bean gum and xanthan gum. The transitional phrase "consists of" excludes any ingredient not specified in the claim (MPEP 2111.03).

Thus, the base of claim 8 does not contain polyacrylic acid or a partly neutralized product or a salt thereof, as in the reference. Moreover, the reference does not suggest using a combination of carrageenan, carob bean gum and xanthan gum in the base without a phosphate buffer. Therefore, the reference does not disclose or suggest the composition of claim 8.

Furthermore, as discussed above, Comparative experiment B of the Declaration submitted April 16, 2007 demonstrates that when a combination of κ-carrageenan, carob bean gum and xanthan gum is used, the syneresis is drastically and unexpectedly improved, compared with a combination of only carrageenan and carob bean gum.

Accordingly, the presently claimed invention is completely different from the Ninomiya et al. reference, and one of ordinary skill in the art would have had no reason to combine the reference with Nagasaka et al. and Fujimaki et al. to arrive at the presently claimed invention.

San-Ei Chem (JP 54-70420)

Applicants submit herewith an English translation of the San-Ei Chem reference.

According to the Examiner, the reference "teaches binder for pharmaceutical preparation with xanthan gum and locust bean (carob bean gum) or carrageenan at 5-10 part of mixture of xanthan gum and locust bean gum (1-10:1-10) of carrageenan (Abstract), which can be converted into 1-10 w/w% xanthan gum and locust bean gum" (see Office Action, page 4 lines 7-10).

A reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention (MPEP 2141.02.VI.). As shown in the English translation, the reference relates to a binder for a medical formulation containing an aqueous gel **consisting of xanthan gum and locust bean gum**, or an aqueous gel **consisting of carrageenan** as a binder (see page 2, lines 10-12). Further, the reference teaches "When xanthan gum or locust bean gum is **singly used**, they do not form any gel even if they are made a hydrous state. Therefore xanthan gum and locust bean gum **must be used in combination**…Carrageenan can be singly used" (emphasis added) (see page 2, lines 13-18).

The reference does not disclose or suggest the combination of xanthan gum, locust bean gum and carrageenan, and does not provide any example thereof. Moreover, there would have been no reason to combine these three components, because carrageenan can form a gel even if it is used alone.

The reference does not disclose or suggest a Chinese herbal medical composition in the form of jelly, which improves syneresis and has superior long term preservative stability by using the combination of xanthan gum, locust bean gum and carrageenan.

Accordingly, the presently claimed invention is completely different from the San-Ei Chem reference, and one of ordinary skill in the art would have had no reason to combine the reference with Nagasaka et al., Fujimaki et al. and Ninomiya et al. to arrive at the presently claimed invention.

In view of the foregoing, one of ordinary skill in the art would recognize that the references do not disclose or suggest a Chinese herbal medical composition in the form of jelly, which improves syneresis and has superior long term preservative stability, by using the combination of xanthan gum, locust bean gum and carrageenan.

Accordingly, the Chinese herbal medical composition of claim 8 would not have been obvious over the references.

Claims 10 and 11 depend from claim 8, and thus also would not have been obvious over the references.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Conclusion

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing remarks, it is submitted that the rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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Enclosures:
(1) Nagasaka et al., Efficacy of Kakkon-to, a Traditional Herb Medicine, in Herpes Simplex Virus Type 1 Infection in Mice, J. Med. Virology, Vol. 46, pp. 28-34 (1995).
(2) English translation of Japanese Patent Publication No. Sho. 54-70420.